K 121327



FEB 0 1 2013

# 510(k) Summary
## for **Diolase™ 10S** by Biolase Technology, Inc.
## (As required by 21CFR 807.92)

1. GENERAL INFORMATION

| | |
|---|---|
| Date Prepared: | January 30, 2013 |
| Company: | Biolase Technology, Inc.<br>4 Cromwell<br>Irvine, CA 92618<br>Tel: (949) 361-1200<br>Fax: (949) 273-6687 |
| Submitter: | Marcia VanValen<br>Director of Business Development<br>Tel: (949) 226-8159<br>e-mail: mvanvalen@biolase.net |
| Contact: | Colleen Boswell<br>VP of Regulatory Affairs<br>Tel: (949) 226-8470<br>e-mail: cboswell@biolase.net |

2. NAMES / REGULATIONS

| | |
|---|---|
| Trade/Device Name: | **Diolase™ 10S** |
| Common Name: | Diode Laser |
| Regulation Number: | 21CFR 878.4810 |
| Classification name: | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Regulatory Class: | II |
| Product Code: | GEX |

## 3. PREDICATE DEVICES

- (K100558) Quanta System QUANTA Diode Laser Family by Quanta System SpA
- (K110375) Blueshine GOLD Series by Blueshine srl
- Reference Device - (K061898) ***ezlase™*** by Biolase Technology, Inc.
- Reference Device - (K083069) ***ezlase™ 10W*** by Biolase Technology, Inc.

## 4. DEVICE DESCRIPTION

The **Diolase™ 10S** system uses an Indium Gallium Arsenide Phosphorous (InGaAsP) solid state laser diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to a hand piece that emits the energy to the target site. A visible light is emitted at the same time to visually identify the treatment location. The **Diolase™ 10S** laser consists of two permanently connected components: Console, and Delivery System. The Console has a Control Panel (Touch Screen and Keypad) in front and a detachable base attached at the bottom rear of the Console. **The Diolase™10S** Laser Delivery System consists of the following: Fiber Optic Assembly and Surgical Handpiece

## 5. INDICATIONS FOR USE

**Expanded Indications for Use:**

***Ear, Nose and Throat and Oral Surgery:***
Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity, such as:

- Removal of benign lesions from ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in-situ
- Ablation and vaporization of hyperkeratosis
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

***Arthroscopy:***
Hemostasis, incision, excision, coagulation, vaporization, and ablation of joint tissues during arthroscopic surgery, such as:

- Menisectomy
- Syovectomy
- Chondromalacia

***Gastroenterology:***
Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy, such as:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps
- Hemostasis of colonoscopy
- Hemostasis of esophageal varices

***Orthopedics***

- Dissect and coagulate

***General Surgery, Dematology & Plastic Surgery, and Podiatry:***
Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of Keloids
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcer
- Dermabrasion
- Vaporization & hemostasis of capillary hemangioma
- Excision, vaporization & hemostasis of abdominal tumors
- Excision, vaporization & hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystecomy
- Thyroidectomy
- Resection of organs

***GI/GU:***
Excision, vaporization, and hemostasis of abdominal and rectal tissues, such as:

- Hemorrhoidectomy
- Excision, vaporization, and hemostasis of rectal pathology
- Excision, vaporization, and hemostasis of abdominal tumors

***Gynecology:***
Ablation, excision, incision, coagulation, hemostasis, and vaporization of tissue, such as:

- Excision or vaporization of condylomata acuminata
- Vaporization of CIN (cervical intraepithelial neoplasia)
- Cervical conization
- Menorrhagia
- Myomectomy
- Ovarian cystectomy

***Neurosurgery:***
Vaporization, coagulation, excision, incision, ablation and hemostasis of tissue, such as:

- Hemostasis in conjunction with meningiomas
- Percutaneous Disc Decompression (PLDD)

***Ophthalmology:***

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor Excision
- Blepharoplasty

***Pulmonary Surgery:***
Hemostasis, vaporization, coagulation, incision, ablation, and excision of tissue, such as:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction

***Cardiac Surgery:***

- Coagulation and hemostasis of cardiac tissue

***Thoracic Surgery:***

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

***Urology:***
Hemostasis, vaporization, incision, coagulation, ablation, and excision of tissues, such as:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia
- Circumcision
- Vaporization of the prostate to treat benign prostate hyperplasia (BPH)

***Dermatology/Aesthetics:***

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, venulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminate, warts, small non-malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcoma. Warty leucoplasty and ulcers debridement.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment

***Vascular Surgery:***

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, venulectasia of the legs and face
- Treatment of reticular veins and branch varicosities

6. DEVICE TECHNOLOGICAL CHARACTERISTICS

The **Diolase™ 10S** system has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices; a summary of the technological characteristics of this device in comparison to those of the predicate devices is included in the body of the 510(k) submission.

7. PERFORMANCE ASSESSMENT

Non-clinical performance data is not presented. Comparison with previously cleared devices is included in the body of the 510(k) submission for the demonstration of safety and effectiveness of the new indication of this device and to support substantial equivalence to legally marketed devices.

8. CONTRAINDICATIONS

*The contraindications are identical to that of the previously cleared **ezlase**™ system by Biolase Technology, Inc.*

All clinical procedures performed with **Diolase™ 10S** must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, malignancies, bleeding disorders, sleep apnea, immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

9. SUBSTANTIAL EQUIVALENCE

The purpose of this 510(k) submission is to add indications for use to the previously cleared ***ezlase™*** diode laser system and market it as **Diolase™ 10S.** The requested additional indications have been cleared by FDA for several equivalent medical devices, including the following: K100558 (Quanta System QUANTA Diode Laser Family by Quanta System SpA) and K110375 (Blueshine GOLD Series by Blueshine srl). Based on comparison, the **Diolase™ 10S** system is substantially equivalent to previously cleared devices.

10. CONCLUSION

The indications requested by this 510(k) submission is the same as those previously cleared by FDA for other predicate devices. Substantial Equivalence for the **Diolase™ 10S** system has been determined through comparison to previous cleared devices. This summary demonstrates that the **Diolase™ 10S** system is as safe, as effective, and will perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Biolase Technology, Incorporated
% Ms. Marcia Van Valen
Director of Business Development
4 Cromwell
Irvine, California 92618-1816

February 1, 2013

Re: K121327
Trade/Device Name: Diolase 10S
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 02, 2013
Received: January 25, 2013

Dear Ms. Valen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours, For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number:** K121327

**Device Name:** **Diolase 10S**

**Indications for Use:**

***Ear, Nose and Throat and Oral Surgery:***
Hemostasis, incision, excision, ablation, and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity, such as:

- Removal of benign lesions from ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in-situ
- Ablation and vaporization of hyperkeratosis
- Laryngeal papillectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

***Arthroscopy:***
Hemostasis, incision, excision, vaporization, and ablation of joint tissues during arthroscopic surgery, such as:

- Meniscectomy
- Synovectomy
- Chondromalacia

***Gastroenterology:***
Hemostasis, incision, excision, and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy, such as:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps
- Hemostasis of colonoscopy
- Hemostasis of esophageal varices

Prescription Use **X** AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Neil R Ogden
2013.02.01 10:17:59 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K121327

***Orthopedics***

- Dissect and coagulate

***General Surgery, Dematology & Plastic Surgery, and Podiatry:***
Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of Keloids
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcer
- Hepatobiliary
- Mastectomy
- Dermabrasion
- Vaporization & hemostasis of capillary hemangioma
- Excision, vaporization & hemostasis of abdominal tumors
- Excision, vaporization & hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorrhaphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystecomy
- Thyroidectomy
- Resection of organs

Prescription Use **X** AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Neil R Ogden
2013.02.01 10:19:05 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K121327

*GI/GU:*
Excision, vaporization, and hemostasis of abdominal and rectal tissues, such as:

- Hemorrhoidectomy
- Excision, vaporization, and hemostasis of rectal pathology
- Excision, vaporization, and hemostasis of abdominal tumors

*Gynecology:*
Ablation, excision, hemostasis, and vaporization of tissue, such as:

- Excision or vaporization of condylomata acuminata
- Vaporization of CIN (cervical intraepithelial neoplasia)
- Cervical conization
- Menorrhagia
- Ovarian cystectomy

*Neurosurgery:*
Vaporization, coagulation, excision, incision, ablation and hemostasis of tissue, such as:

- Hemostasis in conjunction with meningiomas
- Percutaneous Disc Decompression (PLDD)

*Ophthalmology:*

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor Excision
- Blepharoplasty

*Pulmonary Surgery:*
Hemostasis, vaporization, and excision of tissue, such as:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction

*Cardiac Surgery:*

- Coagulation and hemostasis of cardiac tissue

Prescription Use **X** AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Neil R Ogden
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(Division Sign-Off)
Division of Surgical Devices
510(k) Number K121327

*Thoracic Surgery:*

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

*Urology:*

Hemostasis, vaporization, incision, coagulation, ablation, and excision of tissues, such as:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia
- Circumcision
- Vaporization of the prostate to treat benign prostate hyperplasia (BPH)

*Dermatology/Aesthetics:*

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, venulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminate, warts, small non-malignant skin tumors, small semi-malignant tumors as basaliomas, Bowe, Kaposi sarcoma. Warty leucoplasty and ulcers debridement.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment

Prescription Use **X** AND/OR Over-the-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Neil R Ogden
2013.02.01 10:20:55 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K121327

*Vascular Surgery:*

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, venulectasia of the legs and face
- Treatment of reticular veins and branch varicosities

Prescription Use **X** AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Neil R Ogden
2013.02.01 10:22:04 -05'00'

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K121327